



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,979	12/08/2003	Tomoya Miyakawa	Q78853	2814

23373 7590 10/12/2006

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

ZHOU, SHUBO

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/728,979

Applicant(s)

MIYAKAWA ET AL.

Examiner

Shubo (Joe) Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7,9-13,16,17,19-23,26,27,29-33,36,37,39-43,46,47,49-53,56,57 and 59-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/8/03, 2/2/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 4,5,8,14,15,18,24,25,28,34,35,38,44,45,48,54,55 and 58.

DETAILED ACTION

Election/Amendments

Applicants' election, without traverse, of species A (visual characteristics are added based on the degree of mutations and/or similarities) and species D (visual characteristics are displayed using display color) in the response filed 8/23/06 is acknowledged. The following claims read on the elected species and the genus, and are thus under consideration: claims 1-3, 6-7, 9-13, 16-17, 19-23, 26-27, 29-33, 36-37, 39-43, 46-47, 49-53, 56-57, and 59-63.

Claims 4-5, 8, 14-15, 18, 24-25, 28, 34-35, 38, 44-45, 48, 54-55, and 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/23/06.

Sequence Rules Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). Such sequences are present in Figures 7-8, 10 and 12. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because a paper copy, a computer readable form of a Sequence Listing containing this sequence, and a statement under 37 CFR 1.821(f) are not provided. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action including providing a paper copy, a computer readable form of a Sequence Listing containing this sequence, and a statement under 37 CFR

1.821(f). Applicants are reminded that it is required that SEQ ID Nos be amended into the specification at each sequence, and that when a sequence is presented in a drawing regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings. Failure to comply with these requirements may result in ABANDONMENT of the application under 37 CFR 1.821(g).

Information Disclosure Statement

The Information Disclosure Statements filed 12/8/03 and 2/2/05 have been entered and documents listed therein have been considered. Initialed copies of the form PTO-1449 are enclosed with this action.

Drawings

As set forth above, the Drawings filed 12/8/03 contain sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), but the application is not in compliance with 37 CFR 1.821 through 1.825. If applicant chooses to amend the drawings to include sequence identifiers, applicant is advised that replacement drawing sheets in compliance with 37 CFR 1.121(d) are required. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where

Art Unit: 1631

necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to because of the following:

Trademarks are used in this application, such as ENTREZ on page 2. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to also because it contains an embedded hyperlink and/or other form or browser-executable code. Such code is present in the specification at least on page 2. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP ' 608.01.

Appropriate correction is required.

Claim Rejections-35 USC § 101

35 U.S.C. 101 reads as follows:

Art Unit: 1631

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 6-7, 9-13, 16-17, 19-23, 26-27, 29-33, 36-37, 39-40, and 62-63 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-3, 6-7, 9-13, 16-17, 19-23, 26-27, 29-33, 36-37, 39-40 are drawn to a process, or a computer program product or recording medium for sequence display. The process comprises accepting information relating to mutations/similarities between a plurality of sequences and adding visual characteristics and displaying the sequences. Note that the displaying step is to display the original plurality of sequences and they could be the sequences without having visual characteristics added on. The homology searching process comprises analyzing a query sequence to a sequence database, generating search conditions, analyzing the search results and generating information relating to mutations/similarities in plurality of sequences, and using the information generated and displaying the sequences. Claims 62-63 are drawn to a computer program product or a recording medium comprising the program for sequence searching.

The following analysis of facts of this particular patent application follows the rationale suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at <http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm>).

The Guidelines states:

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- The claimed invention "transforms" an article or physical object to a different state or thing.

- The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.

In the instant case, at least one embodiment of the claimed invention merely manipulates sequence data without transforming an article or physical object to a different state or thing outside a computation device.

Furthermore, the invention does not produce a useful, concrete and tangible result. Specifically it does not produce a tangible result. While the claimed process comprising a displaying step, at least one embodiment is to display the original plurality of sequences do not have the visual characteristics added on. Thus, at least one embodiment of the process merely manipulates sequence data without using or making available for use the results of the manipulation to enable its functionality and usefulness to be realized.

Additionally, claims 21-23, 26-27, 29-33, 36-37, 39-40, and 62-63 are drawn to
“computer program product” or “recording medium.” Absent an explicit definition for the term “computer program product” indicating otherwise, the term is interpreted as including merely a computer program, i.e. the software, without being on a computer readable medium. A computer program, per se, i.e. the software, is nonstatutory. Since the specification does not provide an explicit definition for the term “recording medium,” it is interpreted as including any medium where a computer program can be recorded on including a piece of paper. Thus, even though the computer program is recorded on a medium, since it is not required that the medium be a computer readable medium, there is no functional relationship between the program and a computer. Therefore, at least one embodiment of the invention, such as a paper with the program written thereupon, is still just the computer program itself, which is nonstatutory.

Claim Rejections-35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6-7, 9-13, 16-17, 19-23, 26-27, 29-33, 36-37, 39-43, 46-47, 49-53, 56-57, and 59-63 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a step of “adding visual characteristics.” However, it is not clear where to add the visual characteristics. It could be that the visual characteristics are added to the plurality of sequences or to the information relating to mutations and/or similarities.

Claim 1 also recites a step of “displaying said plurality of similar nucleotide sequences or amino acid sequences.” There is no clear antecedent basis for the limitation “said plurality of similar nucleotide sequences or amino acid sequences.” In light of the indefiniteness set forth above, there could be sequences that have the visual characteristics added and sequences without having the visual characteristics added. Thus, it is not clear what plurality of sequences are to be displayed.

Claims 41-43, 46-47, 49-53, 56-57, and 59-63 recite a forth, fifth, sixth and seventh step or mean. It is unclear what are the first, second and third steps or means.

Clarification of the metes and bounds of the claims is requested.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-7, 9-13, 16-17, 19-23, 26-27, 29-33, 36-37, 39-40 are rejected under 35 U.S.C. § 102(b) as being anticipated by Thompson et al. (Nucleic Acids Research, Vol. 25, pages 4876-4882, 1997).

Claims 1-3, 6-7, 9-13, 16-17, 19-23, 26-27, 29-33, 36-37, 39-40 are drawn to a sequence display process, or a computer program product or recording medium for the process. The sequence display process comprises accepting information relating to mutations/similarities between a plurality of sequences and adding visual characteristics and displaying the sequences. Note that the displaying step is to display the original plurality of sequences and they could be the sequences without having visual characteristics added on.

Thompson et al. disclose a sequence search and display method, referred to as CLUSTAL X. The method comprises a sequence display mechanism where visual characteristics, i.e. color, is added to the sequences where the similarities among a plurality of amino acid sequences reside after information relating to similarities among a plurality of sequences are obtained. See Fig. 1. Note that the copy of the cited reference by Thompson et al. is a black and white copy. However, a version of the reference with the original colors can be obtained online from the website with the following URL: <http://nar.oxfordjournals.org/cgi/reprint/25/24/4876>.

As to claims 2-9, as can be seen from the color version of Fig. 1, in the alignment of a plurality of amino acid sequences, multiple different colors are used to indicate sequences of homology shared by the plurality of sequences. For example, yellow color is added to show "P." And the color is added according to degree of similarities. For example, yellow is only used for the identical sequence, i.e. 100% homology, "P," whereas purple is used for less homologous sequences such as "D" and "E," which are not identical but both belong to acidic residue group. The colors are added using pull-down "colors" menu. See Fig. 1.

As to claim 10, the method comprises link for related information of the sequences. For example, to the left side of each sequence (see Fig. 1), there is the name of the sequence that is linked to the sequence.

As to claims 11-13, 16-17, 19-23, 26-27, 29-33, 36-37, 39-40, which are drawn to a device and computer program for the sequence display, Thompson et al. disclose all necessary systems, devices and computer software needed for CLUSTAL X. See page 4877, left column. Further, Thompson et al. state that "The CLUSTAL X code is written in ANSI C, and should be portable to any machine capable of supporting the NCBI Vibrant toolkit. CLUSTAL X is available for a number of platforms including SUN Solaris, IRIX ... The source code is provided for anyone wishing to port to any other platform supported by the Vibrant project." Thompson et al. also provide the hyperlinks for downloading the source codes. See page 4877, left column. Therefore, Thompson et al. disclose the device and computer program for the method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 41-43, 46-47, 49-53, 56-57, and 59-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Genome Research, Vol. 7, pages 649-656, 1997) in view of Thompson et al. (Nucleic Acids Research, Vol. 25, pages 4876-4882, 1997) as applied to claims 1-3, 6-7, 9-13, 16-17, 19-23, 26-27, 29-33, 36-37, 39-40 above.

The claims are drawn to a process or device or computer program for performing the process for homology search. The process includes analyzing a query to a database, generating search conditions,

Zhang et al. disclose a method, device and computer program for conducting nucleic acid or amino acid sequence searches, referred to as PowerBLAST. The method comprises analyzing a query sequence by identifying and filtering repetitive subsequences in the query, generating different search conditions such as BLASTN, BLASTP, BLASTX or TBLASTN with specific parameters. If the query sequence is large, it is split into overlapping pieces and the results are merged. See page 654, and Figs 5 and 6. The method also comprises analyzing the search results

Art Unit: 1631

to generate organism specific results and more sensitive gapped alignments. See page 649, right column, last paragraph.

However, Zhang et al. do not teach displaying the search results using a method as in claim 1, i.e. a method comprising accepting information relating to mutations/similarities between a plurality of sequences and adding visual characteristics and displaying the sequences.

As applied to claims 1-3, 6-7, 9-13, 16-17, 19-23, 26-27, 29-33, 36-37, 39-40 above, Thompson et al. disclose a method, device and computer program for sequence display comprising accepting information relating to mutations/similarities between a plurality of sequences and adding visual characteristics and displaying the sequences. Thompson et al. design a pull-down menu for using multiple colors for the alignment display. Thompson et al. state that the coloring system used to highlight conserved residue features in the alignment is versatile and configurable. See page 4877, left column, top paragraph.

One of ordinary skill in the art would have been motivated by Thompson et al. to modify the method disclosed by Zhang et al. to use the display system by Thompson et al. to display the sequence search results because the system of Thompson et al., in addition to its features of “easy to use, providing an integrated system for performing multiple sequence and profile alignments and analyzing the results (see Abstract),” includes the coloring system for easy recognition of different conserved residues in the aligned sequences. And the coloring system is easy to use as it contains a pull-down menu. Therefore, a homology searching method, device and computer program as claimed in the instant claims 41-43, 46-47, 49-53, 56-57, and 59-63 would have been obvious to one having ordinary skill in the art at the time the invention was made over the combination of Zhang et al. and Thompson et al.

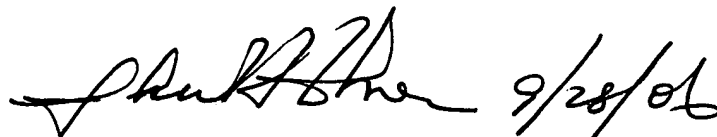
Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D.
Patent Examiner

Handwritten signature of Shubo (Joe) Zhou and the date 9/28/06.